

Docket No. GYN0116USCIP

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Michael R. Tracey

Serial No. : 10/674,452 Art Unit: 0

Filed : September 30, 2003 Examiner: N/A

For : A SYSTEM AND METHOD FOR ASSESSING DETRUSOR INSTABILITY

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

Nov 7<sup>th</sup> 2003  
(Date of Deposit)

Melissa J. Szanto  
(Name of applicant, assignee, or Registered Representative)

Melissa Szanto  
(Signature)

Nov. 7 2003  
(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with  the first or  second After Final Submission, therefore:

- Statement in Accordance with §1.97(e)  
(attached); or
- Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- Statement in Accordance with §1.97(e)  
(attached); or
- Please charge Deposit Account No. 10-  
0750/ / the fee of \$180.00 as set forth  
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In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

- Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
  - In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
  - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
- Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not

enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

There are no listed references which are not in the English language.

The relevance of those listed references which are not in the English language is as follows:

Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/GYN0116USCIP/MJS. This form is submitted in triplicate.

Respectfully submitted,

  
\_\_\_\_\_  
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DATED: *Nov. 7, 2003*



.PTO/SB/08A (08-00)

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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

Application Number	10/674,452
Filing Date	September 30, 2003
First Named Inventor	Michael R. Tracey
Group Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	GYN-0116USCIP

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		4367740	A	Evanoski	01/11/1983	
		6447462		Wallace et al.	09/10/2002	
		6056699		Sohn et al.	05/02/2000	
		5566680		Urion et al.	10/22/1996	
		6071230		Henalla	06/06/2000	
		5449345		Taylor et al.	09/12/1995	
		5331548		Rollema et al.	07/19/1994	
		5176148		Wiest et al.	01/05/1993	
		0045355		Gephart et al.	11/29/2001	
		5868135	A	Kaufman	02/09/1999	
		4998527	A	Meyer	03/12/1991	
		6258087	B1	Edwards	07/10/2001	

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
		EP	0608593	A1	Medidenta B.V.	08/03/1994		X
		EP	0878166	A1	Lourdel et al.	11/18/1998		
		WO	00/23127	A1	Surx, Inc.	04/27/2000		X

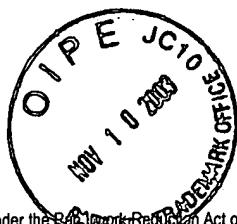
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**Substitute for form 1449A PTO**

<i>Application Number</i>	10/674,452
<i>Filing Date</i>	September 30, 2003
<i>First Named Inventor</i>	Michael R. Tracey
<i>Group Art Unit</i>	N/A
<i>Examiner Name</i>	N/A
<i>Attorney Docket Number</i>	GYN-0116USCIP

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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U.S. PATENT DOCUMENTS

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		Number	Kind Code <sup>2</sup> (if known)			
		4217911		Layton	08/19/1980	
		5954696		Ryan	09/21/1999	
		5823972		McRae	10/20/1998	
		5377101		Rollema	12/27/1994	
		4612939		Robertson	09/23/1986	
		4191196		Bradley et al.	03/04/1980	
		4464172		Lichtenstein	08/07/1984	
		4370983		Lichtenstein	02/01/1983	
		4484585	A	Baier	11/27/1984	
		6461332		Mosel et al	10/08/2002	

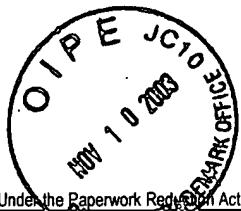
## **FOREIGN PATENT DOCUMENTS**

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<i>Application Number</i>	10/674,452
<i>Filing Date</i>	September 30, 2003
<i>First Named Inventor</i>	Michael R. Tracey
<i>Group Art Unit</i>	N/A
<i>Examiner Name</i>	N/A
<i>Attorney Docket Number</i>	GYN-0116USCIP

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Sheet 3 of 4**

## **U.S. PATENT DOCUMENTS**

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		Number	Kind Code <sup>2</sup> (if known)			
		6,283,987		Laird	09/04/2001	
		2002/0115906	A1	Miller	08/22/2002	
		2003/0027326	A1	Ulmsten et al.	02/06/2003	
		2003/0028074	A1	Tracey et al.	02/06/2003	
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		2002/0111586	A1	Mosel	08/15/2002	

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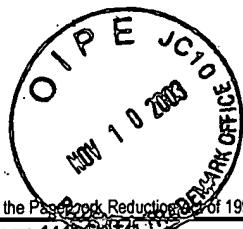
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
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Sheet 4 of 4

<i>Application Number</i>	10/674,452
<i>Filing Date</i>	September 30, 2003
<i>First Named Inventor</i>	Michael R. Tracey
<i>Group Art Unit</i>	N/A
<i>Examiner Name</i>	N/A
<i>Attorney Docket Number</i>	GYN-0116USCIP

<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>			
<b>Examiner's Initials*</b>	<b>Cite No.<sup>1</sup></b>	<b>Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published</b>	<b>T<sup>2</sup></b>
		ORDORICA, RAUL C. "Choosing the right urodynamic system", Contemporary Urology, 1996, pages:47-64.	X
		BARNES, D.G. et al., "A consumer's Guide to Commercially Available Urodynamic Equipment", British Journal of Urology, 1991, 68, pages 13-143.	X
		ROWAN, D. et al., "Urodynamic equipment: technical aspects" Journal of Medical Engineering & Technology, 1987, pages 57-64, Vol. 11.	X
		Surgitek® UDS-1000G, A Systems Approach, The Journal of Urology 1992, AUA Eighty-Seventh Annual Meeting, Washington, D.C.	X
		UroBase™ The Portable Cystometer. The Journal of Urology 1989, Number 1, Vol. 141, Annual Meeting, American Urological Association, Inc., Dallas, Texas.	X
		UDS-54, The Urodynamics System, The Journal of Urology 1989, Vol. 141, Number 4, Part 2, AUA Eighty-Fourth Annual Meeting, Dallas, Texas.	
		Bard 4-Channel Urodynamic Monitor, A Breakthrough In Urodynamic Technology, Bard Urological Division, C.R. Bard, Inc. 1995.	X
		Market Engineering Research for the U.S. UI Urodynamic Equipment Market, Frost & Sullivan 1998.	X
		The Dantec Duet™, 510(k) Summary of Safety and Effectiveness (1996)	X
		The Lumax Fiber Optic Pressure Monitoring System, 510(k) Summary, 1995.	X
		PETROS, P.E.P. et al., An Integral Theory And Its Method For The Diagnosis And Management Of Female Urinary Incontinence, Scandinavian Journal of Urology and Nephrology, 1993, Supplement 153,	X
		LANE, T.M. et al., Leak-point pressures, BJU International 2000, Vol. 86, pages 942-949.	X
		MCLENNAN, M.T. et al., Leak-Point Pressure: Clinical Application of Values at Two Different Volumes, International Urogynecology Journal, 2000, Vol. 11, pages 136-141.	X
		PETROS, P.E.P. et al., An Anatomical Classification - a New Paradigm for Management of Urinary Dysfunction in the Female, International Urogynecology Journal, 1999, Vol. 10, pages 29-35.	X
		PETROS, P.E.P. et al., An anatomical classification - a new paradigm for management of female lower urinary tract dysfunction, European Journal of Obstetrics & Gynecology and Reproductive Biology, 1998, Vol. 80, pages 87-94.	X
		KIM, K.J. et al., The Vesico-Urethral Pressuregram analysis Of Urethral Function Under Stress, 1997, Vol. 30, No. 1, pages 19-25.	X
		SANCHEZ-DOBLADO, F. et al., Computerized analysis of urological parameters, Medical & Biological Engineering & Computing, 1988, Vol. 26, pages 325-327.	X
		KIM, K-J. et al., Principles of urodynamics pressure measurement and its implication to female continence function, Journal of Biomechanics, 1998, Vol. 31, pages 861-865.*	
		Lumaxpro Fiberoptic Cystometry System, Cooper Surgical, Shelton, CT.	X
		Andromeda, Ellipse, The modular concept for precise urodynamics, Timm Medical Technologies, Inc. Eden Prairie, MN	X
		BONNEY et al., Historical Presentation, Berlin-Brandenburgische 2002.	X
			X

<b>Examiner Signature</b>	<b>Date Considered</b>
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